UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875
	Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	**ORAL ARGUMENT REQUESTED**

TEVA DEFENDANTS' OMNIBUS MOTIONS IN LIMINE

Pursuant to the Federal Rules of Evidence, the Teva Defendants ("Teva") move to preclude certain evidence and argument they anticipate Plaintiffs may offer at trial primarily impacting Teva.

LEGAL STANDARDS

Teva incorporates herein by reference the legal standards generally applicable to motions in limine under the Federal Rules of Evidence detailed in the parties' joint omnibus motion in limine. *See* TPP Trial Defendants' Motions in Limine at 1.

ARGUMENT

A. The Toxikon Report Should Be Excluded.

In 2014, Teva contracted a third-party, Toxikon, to perform testing on a *rubber stopper* (i.e., the rubber seal component of a medicine packaging system) to determine the amount of extractable nitrosamines in the rubber stopper. *See* **Ex. A**, Toxikon Report, TEVA-MDL2875-00917708 - TEVA-MDL2875-00917715, at 1.

Based on Plaintiffs' questioning of Teva's corporate witness Dan Barreto, Teva anticipates that Plaintiffs may seek to introduce or reference this report to argue that Teva was aware of the potential for nitrosamine formation or had developed tests in 2014 that could be used to detect nitrosamines in its *valsartan-containing drugs* ("valsartan" or "VCDs") based on this report from an external company revealing nitrosamines in the *rubber stopper*. The fact that Teva contracted with a company to perform testing on ***rubber packaging materials***, based on knowledge in the rubber industry that nitrosamines may form in rubber materials, has no bearing on whether Teva could have anticipated the formation of or performed similar testing to detect nitrosamines in pharmaceuticals. As Mr. Barreto testified:

[redacted]

Ex. B, Deposition of Dan Barreto (Apr. 15, 2021) ("Barreto Dep. Vol. II") 793:24-794:19.

The testing that Teva had Toxikon perform on a rubber stopper is irrelevant to the issues in this trial and should be precluded. *See* Fed. R. Evid. 402. It has no bearing on whether Teva had the capability in 2014 to perform testing of its products

that would have detected nitrosamines at the levels later found in valsartan, much less whether Teva had any reason to do so. Indeed, ***Plaintiffs' own experts*** testified that neither API nor finished-dose manufacturers would have detected the NDMA later found in valsartan through routine chromatography testing (even using GC-MS), and that the presence of NDMA in valsartan was unexpected. *See, e.g.*, **Ex. C**, Deposition of Stephen Hecht (Jan. 13, 2023) ("Hecht 2013 Dep.") 274:5-11; *see also* **Ex. D**, Deposition of Philip Russ (Jan. 5, 2023) 192:17-193:4 ("Q: 'Because it was not anticipated that NDMA would occur at these levels in the manufacturing of the Valsartan API, manufacturers would not have tested for it.' . . . that's a statement issued by FDA; correct? A: It is. Q: Do you disagree with that statement? A: I don't disagree with this statement. It was unexpected[.]").

Introduction of the Toxikon report would serve no purpose than to confuse the issues for the jury and unfairly prejudice Teva. *See* Fed. R. Evid. 403. Such a diversion would unnecessarily expand the trial into discussions of nitrosamine formation in rubber and the vast differences between the testing developed for rubber and pharmaceuticals. The Toxikon report and related testimony should be precluded.

B. The HHA for Valsartan, and Any Draft, Should Be Excluded.

After ZHP notified Teva of the presence of NDMA in its valsartan API in June of 2018, Teva prepared and issued a Health Hazard Assessment ("HHA") for its valsartan products. **Ex. E**, TEVA-MDL2875-00057086; **Ex. F** TEVA-

MDL2875-00274341. Plaintiffs questioned Teva's witness Dr. Raphael Nudelman on the draft of this HHA during his deposition. *See* **Ex. G**, Deposition of Raphael Nudelman (Apr. 8, 2021) 154:17-21. Plaintiffs should be precluded from introducing or referencing the HHA or any drafts of it at trial as it is irrelevant, and any possible relevance would be substantially outweighed by the potential for unnecessary expansion of the trial, jury confusion, and unfair prejudice. Fed. R. Evid. 402, 403.

For context, the HHA references specific instances of individuals' exposure to huge amounts of NDMA, from sources other than pharmaceuticals, resulting in their sudden deaths.[1] For example, they discuss a woman who died of liver failure after being *intentionally poisoned* with NDMA, and two people who died of liver failure and cerebral hemorrhage *within days* after they consumed tainted lemonade. *See* **Ex. H,** TEVA-MDL2875-00329227. The examples in the HHA do not relate to *trace amounts* of NDMA in a *medication* (which still provided the intended therapeutic value) purportedly resulting in the development of cancer. They relate to *lethal doses* of NDMA leading to *sudden death*:

> [One person] was *intentional[ly] poison[ed]* with at least 4 doses as high as 250-300 mg each. . . . Another adult male and a 1-year old boy died *[within] days* after consuming lemonade tainted with NDMA. The adult might have received about 1.3 gram[s] and the boy might have received about 300 mg.

[1] The reports of these individuals' adverse events contained in the HHAs are also hearsay if offered by Plaintiffs as evidence that these individuals in fact experienced the health events described. *See* Fed. R. Evid. 802.

See id. The extremely high doses of NDMA in these examples simply cannot be compared to the trace amounts found in Teva's VCDs. As concluded in FDA's laboratory testing results of the recalled valsartan lots, the highest level of NDMA in any of Teva's recalled valsartan products ranged from 7.92-16.55 *micrograms*. *See Laboratory Analysis of Valsartan Products*, FDA, https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products (last visited Feb. 15, 2024). The levels of NDMA in the examples referenced in the HHAs are over 15,000 times as high.[2]

Reports of NDMA poisonings have no bearing on Plaintiffs' economic loss claims and would serve no purpose other than to confuse, mislead and inflame the jury, particularly where there are no personal injury claims being tried. Accordingly, evidence, argument, and references to these draft and final HHAs and the adverse events within should be precluded. *See* Fed. R. Evid. 402, 403.

C. ANDA Rescission Letter re: Dr. Reddy's API Should Be Excluded

Long before the nitrosamine impurity issue arose, Teva submitted an ANDA to FDA proposing Dr. Reddy's Laboratories as an API supplier for valsartan. ANDA 077530 was initially approved then rescinded in October 2015, due to FDA's concerns regarding Dr. Reddy's compliance status, which had nothing to do with

[2] To be clear, this is not information that was previously known to Teva, but rather was learned during Teva's toxicology assessment *after* the discovery of the impurities.

nitrosamines. Teva never produced any valsartan products under this ANDA using Dr. Reddy's API supply, and there is no product at issue in this trial, or even this MDL, involving Dr. Reddy's API. Nonetheless, Teva anticipates Plaintiffs will seek to introduce the 2015 FDA letter rescinding ANDA 077530 and Teva's response. *See* **Ex. I**, TEVA-MDL2875-00261415. Plaintiffs' counsel asked Teva's expert:

> Q: And the FDA says that one of Teva's arguments to avoid rescission of its ANDA was that the valsartan API it was using from Dr. Reddy's complied with applicable specifications, as did the finished dose incorporation same. Right? . . .
>
> Q: And if you continue that paragraph onto the next page, the FDA rejects that argument; right? . . .
>
> Q: And the FDA specifically says . . . for a facility to be in compliance with CGMP, it is not enough that the finished drug products, or the APIs used to manufacture such finished drugs, conform to specifications and that testing for such products does not suggest any trends toward being out of specification. . . .
>
> Q: And it further continues . . . a facility must have in place systems that ensure proper design, monitoring, control of manufacturing processes and facilities. . . .

See **Ex. J**, Deposition of Roger Williams (Jan. 31, 2023) ("Williams 2023 Dep.") 111:9-112:16. Plaintiffs are apparently attempting to improperly use the Dr. Reddy's letter to make an irrelevant argument that compliance with specifications does not qualify an API supplier where known cGMP violations exist. However, that point is irrelevant and misleading in the context of the present trial, where ZHP was in fact approved as a supplier in Teva's ANDAs.

The ANDA rescission letter is wholly irrelevant and misleading given Dr. Reddy's API was never used, and the cGMP issues identified by the FDA at Dr. Reddy's are in no way connected to the formation of NDMA in ZHP's valsartan API. The valsartan manufactured under ANDA 077530 was *never marketed*. The letter and any evidence of Teva's position concerning the recission of the ANDA should thus be precluded as irrelevant. Fed. R. Evid. 402. It would also unnecessarily expand the scope of trial, as Teva would be forced to delve into a side-show defending its selection of Dr. Reddy's as a supplier, which is wholly unrelated to Plaintiffs' claims. It should be precluded for that reason as well. Fed. R. Evid. 403.

D. The Bogoslavski Email Chain Should Be Excluded.

Teva anticipates that Plaintiffs may seek to introduce a 2017 email chain in which a Teva employee questioned a ZHP validation report regarding ZHP's method for identifying various solvents in valsartan to argue or elicit testimony that Teva should have more closely scrutinized ZHP as an API supplier. *See* **Ex. L**, TEVA-MDL2875-00521038. For example, Plaintiffs' counsel explored the questions raised in the email chain with defense expert Dr. Roger Williams during his deposition, seeking concessions that a finished-dose manufacturer should have increased its scrutiny of ZHP as an API supplier in light of the questions. *See, e.g.*, Williams 2023 Dep. 254:9-14. But the emails did not relate to valsartan intended to be marketed or

sold in the United States, or to the process that was later determined to have led to the formation of NDMA in the ZHP API at issue.

The scope of this litigation is limited to "the facilities that manufactured Valsartan API and Valsartan sold in the United States. . . ." *See* Macro Discovery Order, dated November 25, 2019 (ECF 303) at 3. The email chain relates to an alternative supplier investigation conducted by Teva Israel for product that was never sold in the United States. It is thus outside the scope of the trial. Further, the validation method discussed is unrelated to nitrosamines and would not have revealed the presence of nitrosamines in the ZHP valsartan API at issue. The email assessed the validation method for determining the presence of the following solvents: methanol, ethanol, DCM, n-hexane, ethyl acetate, toluene, and xylene. *See* TEVA-MDL2875-00521038. Teva had no reason to suspect that nitrosamines could have formed in ZHP's valsartan API based on the validation report. *See, e.g.*, Hecht 2023 Dep. 300:13-301:24 (confirming that the root cause of NDMA in valsartan was the use of sodium nitrite in the sodium azide quenching process). This email chain is thus irrelevant, and Plaintiffs should not be permitted to make arguments or elicit testimony at trial concerning it. Such evidence would also risk jury confusion and unnecessarily expand the trial. *See, e.g.*, *Nicholas v. Pennsylvania State Univ.*, 227 F.3d 133, 148 (3d Cir. 2000).

E. The Guda Email Chain Should be Excluded.

Teva anticipates that Plaintiffs may seek to introduce emails between Teva employees and ZHP employees in which Teva requested a current version of the valsartan drug master file (DMF) to argue or suggest that Teva in fact received the DMF from ZHP and could have predicted the formation of nitrosamines in valsartan API after reviewing it. *See, e.g.*, Williams 2023 Dep. 105:12-17. Plaintiffs should be precluded from making any such arguments because (1) the emails are inadmissible hearsay, and their contents are double hearsay if offered as evidence of what occurred; (2) the emails are irrelevant because they do not establish what portions of the DMF Teva received or when; and (3) there is no probative value because there is no evidence that the hypothetical portions of the DMF sent would have led Teva to predict the formation of NDMA.

First, ***even if*** the email chain itself is admissible, any statements in it are inadmissible hearsay if offered as evidence of the truth of the matter they assert, i.e., that ZHP in fact sent a DMF to Teva in May 2018. *See* Fed. R. Evid. 802. Further, the email chain is also hearsay unless Plaintiff establish that it falls within an exception. For example, "[a]n email created within a business entity does not, for that reason alone, satisfy the business records exception of the hearsay rule." *Roberts Tech. Grp., Inc. v. Curwood, Inc.*, Civil Action No. 14-5677, 2016 U.S. Dist. LEXIS 64538, *4 (E.D. Pa. May 17, 2016). "A party must provide specific foundational

evidence allowing the Court to find the statements to be trustworthy." *Id.* at *5. If Plaintiffs cannot establish that the emails fall within a hearsay exception, they would be double-hearsay if offered as evidence that ZHP in fact sent Teva a DMF.

Second, even setting aside the hearsay problem, the email chain is not evidence of what, if any, portions of the DMF Teva in fact received or when. At most, the emails establish that Teva requested the DMF and that ZHP indicated that a DMF was sent out. *See* **Ex. M,** TEVA-MDL2875-00136091. It does not establish when or if the DMF was received. *See* **Ex. N,** Deposition of Stefan Karlsson (Mar. 18, 2021) ("Karlsson Dep.") 307:20-309:5 (explaining that Teva would normally only have access to the *unrestricted* portions of an the DMF of an API supplier).

Third, the emails have no probative value even if they could be used to show that Teva in fact received a DMF or portions of one—which they cannot. Plaintiffs would be unable to establish anything that Teva could or should have gleaned from this hypothetical DMF, or how the hypothetical information it received would have led it to predict the presence of NDMA in the valsartan API, much less before ZHP did, approximately a month later, in June 2018. The emails will serve only to confuse the jury. Thus, any such evidence or argument should be excluded.

F. The Karlsson Email Should be Excluded.

Plaintiffs should be precluded from introducing or eliciting testimony concerning an email written by Teva employee Stefan Karlsson on October 23, 2018,

in which he outlined his "personal thoughts" on DMF review in preparation for an internal meeting at Teva to discuss "DMF deficiencies in U.S." *See* **Ex. O**, TEVA-MDL2875-00102646. The email includes suggestions for improvements to Teva's DMF review process that "could prevent future Valsartan NDMA issues." *Id.* It should thus be precluded as a subsequent remedial measure under Rule 407. *See, e.g., Complaint of Consolidation Coal Co.*, 123 F.3d 126, 136 (3d Cir. 1997) (stating that "there is authority supporting the exclusion of evidence of post-accident investigations under Rule 407" and affirming exclusion of a memo stating that an employee fell after a line broke and cautioning all employees to inspect ropes carefully before using them"); *Reynolds v. Univ. of Pennsylvania*, No. CIV.A 06-1237, 2010 WL 2253732, at *3 (E.D. Pa. June 2, 2010), aff'd, 483 F. App'x 726 (3d Cir. 2012) ("The primary purpose of Rule 407 is to encourage individuals 'to take, or at least not to discourage individuals from taking, steps in furtherance of added safety.'") (quoting Fed. R. Evid. 407, Advisory Comm.'s Note).

Further, the email is not evidence of Teva's quality department's procedures for DMF review for commercial products like valsartan. Mr. Karlsson worked in Teva's R&D procurement department and had no involvement in the quality processes for Teva's commercial valsartan products in the United States. He readily admitted at deposition that he was not familiar with processes at all of Teva's sites

or practices outside of R&D, including the quality practices for commercial production like that involving valsartan. He testified:

Karlsson Dep. 295:13-296:5 (emphases added).

Accordingly, Plaintiffs should be precluded from arguing, suggesting, or eliciting testimony that Teva's DMF review procedure was somehow inadequate, based on the personal opinions Karlsson expressed in the email. The email should be precluded under Rule 407, and as irrelevant, misleading, and unfairly prejudicial.

G. The Court Should Exclude Teva SOP on Contract Manufacturers.

Plaintiffs may attempt to introduce an irrelevant Teva Standard Operating Procedure (SOP), CORP-00046, governing the relationship between Teva and contract manufacturers of finished-dose products. *See* **Ex. Q**, CORP-00046. Plaintiffs will likely argue or imply, incorrectly, that this SOP applied to Teva's relationship with ZHP, when it did not. Plaintiffs questioned Teva's former head of quality, Dan Barreto, during his deposition on Teva's adherence to this SOP in

regard to ZHP. *See e.g.,* **Ex. P**, Deposition of Dan Barreto (Apr. 14, 2021) ("Barreto Dep. Vol. I") 47:22-67:22. But he explained that this SOP applies to a company contracting to make a finished product for Teva, not a supplier of API like ZHP. *Id.* at 58:2-4-22. In fact, he specifically testified that ZHP was ***not*** a contract manufacturer as defined by CORP-0046, and therefore, the SOP did not apply to it:

> Q. And ZHP, I think you said, was not a contract manufacturer; it was an API supplier? A. It is an API supplier, not a contract manufacturer, within the definition of what the contract manufacturer is. Q. Okay. So would Exhibit-135 [CORP-0046] have -- regarding contract manufacturer have applied to the valsartan API relationship between Teva and ZHP? A: No.

See Barreto Dep. Vol. II 732:4-16.

Because the SOP CORP-0046 does not govern or relate to the API supplier relationship between ZHP and Teva, it is irrelevant and inadmissible under Rules 401, 402, and 403. *See, e.g., Lehmann v. Louisville Ladder Inc.*, 610 F. Supp. 3d 667, 693 (E.D. Pa. 2022) (excluding code of ethics that did not apply to the claims because it would incorrectly suggest a party needed to follow its standards). The Court should thus preclude CORP-0046 and any argument regarding it at trial.

H. The Court Should Exclude References to TAPI.

Teva anticipates that Plaintiffs may attempt to introduce evidence and make argument regarding an entity called Teva Active Pharmaceutical Ingredients (TAPI), an organization within Teva that manufactures its own API. Notably, this Court held that evidence of facilities that did not manufacture valsartan API and finished-dose

valsartan products for sale in the United States was not even *discoverable*. *See* Macro Discovery Order, at 2.[3] And no TAPI API was used in any Teva valsartan product ever marketed in the United States, and no product at issue here was manufactured in a TAPI facility. *See* **Ex. R**, Deposition of Claire Lyons (Apr. 27, 2021) 306:1-6. Any evidence or argument related to TAPI is thus irrelevant to the issues in this trial for the same reasons the Court precluded discovery regarding valsartan API sold only outside the United States in its Macro Discovery Order. *See e.g., Bell v. Lockheed Martin Corp.,* No. 08-6292 (RBK/AMD), 2010 U.S. Dist. LEXIS 96864, at *21 (D.N.J. Sep. 15, 2010).

Even setting aside the Court's Macro Discovery Order, any evidence or argument regarding TAPI is irrelevant and would serve only to create potential juror confusion and needlessly expand the scope of trial. Teva expects that Plaintiffs may try to introduce evidence related to TAPI to argue or insinuate that Teva should have predicted the formation of or detected NDMA in valsartan because of TAPI's knowledge of how valsartan is manufactured. *See, e.g.*, **Ex. S**, Deposition of Steven Baertschi (Jan. 26, 2023) 67:2-14 (questioning Teva process chemistry expert Dr. Steven Baertschi about whether a company that manufactures valsartan API would

[3] In its "Macro Discovery" Order, this Court further denied Plaintiffs' "request for discovery regarding other products using the same manufacturing process, solvents and testing as those for Valsartan API." *See* Macro Discovery Order, at 2. Therefore, even if the "same manufacturing process, solvents, and testing" had been used for the TAPI API and the ZHP API at issue here –which has not been established– the Macro Order indicates that documents related to TAPl are irrelevant.

be generally aware of "how valsartan is made"). But as Dr. Baertschi explained, an API manufacturer's understanding of its own processes does not necessarily translate to the process of a different manufacturer. *See id.* 66:21-23; 67:6-14. Nor have any of Plaintiffs' experts opined that because of the existence of TAPI, Teva as a whole was better able to predict the formation of NDMA in valsartan than if it had not manufactured API through this discrete entity. Evidence regarding TAPI is thus irrelevant to the extent Plaintiffs attempt to introduce it for this purpose.

Relatedly, Teva also anticipates Plaintiffs may attempt to introduce evidence that TAPI developed a method to detect NDMA using gas chromatography with mass spectrometry ("GC-MS"), in July 2018, to argue or imply that Teva could have been testing ZHP API for NDMA using that method and/or equipment before it was informed of the detection of NDMA by ZHP. Such evidence and argument should likewise be excluded as an irrelevant red herring.[4] Teva, like the rest of the industry and the FDA, was unaware of the potential for the presence of NDMA in valsartan until being informed of the detection by ZHP in June 2018. Before then, Teva had no reason to develop a methodology to test ZHP API for NDMA. *See* **Ex. T**, Deposition of Tony Binsol (May 13, 2021) 240:8-15. The Court should preclude evidence related to TAPI as not probative of any issue in this trial.

[4] TAPI's development of a method to test its products for NDMA after the detection of NDMA in ZHP valsartan is also inadmissible as a subsequent remedial measure under Rule 407, since TAPI is an entity within Teva.

I. The Court Should Exclude Evidence or Argument Related to Teva's Commercial Decision to Stop Selling Valsartan.

Teva anticipates that Plaintiffs may argue or insinuate that Teva's commercial decision to stop selling VCDs in November 2018 was because of the detection of nitrosamine impurities and the ensuing recalls and thus a tacit admission of wrongdoing by Teva. Any evidence of Teva's decision to stop selling VCDs should be precluded because it is not relevant to Plaintiffs' claims. Further, any (unsupported) suggestion that Teva stopped selling VCDs in response to the recalls would be inadmissible as a subsequent remedial measure.

Teva's decision to stop selling VCDs is irrelevant to any claim because Teva ceased selling VCDs *after* the products had been recalled and were no longer being sold. *See* **Ex. U**, Deposition of Michelle Osmian, dated May 6, 2021 ("Osmian Dep.") 107:18-24. Such evidence thus would not be probative of Plaintiffs' claimed damages or any other issue to be determined in this trial and should be precluded under Rule 402 for that reason alone. Given the lack of probative value, evidence of Teva's decision to stop selling VCDs would also needlessly waste the jury's time, and the Court should preclude it for that reason as well. *See* Fed. R. Evid. 403.

Despite the lack of relevance, Plaintiffs may try to introduce evidence that Teva stopped selling VCDs to imply that it somehow conceded wrongdoing. As an initial matter, no evidence has been adduced that Teva decided to stop selling VCDs

because of the detection of nitrosamines and subsequent recalls.[5] Regardless, any implication that Teva conceded wrongdoing through its decision to stop selling VCDs would fall squarely within the prohibition of evidence of subsequent remedial measures. *See* Fed. R. Evid. 407.

The Court should thus preclude any evidence of Teva's decision to stop selling VCDs and any argument or suggestion that such a decision was a tacit admission of wrongdoing by Teva. At minimum, if Plaintiffs are allowed to tell the jury that Teva's VCDs are no longer available on the United States market, they should not be allowed to suggest or imply that this is due to the detection of NDMA or any kind of admission by Teva.

J. References to the Timing of Teva's Field Alert Should Be Precluded.

Plaintiffs have asserted through their summary judgment submissions and questioning during depositions that Teva failed to adhere to its own SOPs and federal regulations by failing to issue a Field Alert within three business days of learning of a potential impurity from ZHP. *See* 21 C.F.R. § 314.81; *see also* **Ex. V**, CORP-0092, TEVA-MDL2875-00020376. For example, without citing any record in support, Plaintiffs assert in their Statement of Undisputed Material Facts in Support of Partial

[5] As Ms. Osmian testified in her capacity as vice president of commercial operations, Teva had undertaken a review of their portfolio, including whether the discontinue sales of valsartan, before the recall. *See* Osmian Dep. at 111:7-113:9. Teva then chose to cease production of valsartan for commercial reasons. *Id.* at 107:18-24, 109:12-20, 324:15-325:7.

Summary Judgment that "Teva did not inform the FDA about the potential of NDMA contamination within the time prescribed by its own standard operating procedures." *See* Pl. SUMF (ECF 2566) ¶ 73; *see also, e.g.,* Barreto Dep. Vol. I 251:22-254:1. Teva expects Plaintiffs will attempt a similar argument at trial. But, in addition to being unsupported by the evidence, the timing of the Field Alert is irrelevant as it is not probative of any fact material to Plaintiffs' claims.

The timeliness of the Field Alert is irrelevant to the economic loss damages sought here related to purchase of Teva's VCDs made with ZHP API. Plaintiffs' assertions on the Field Alert's untimeliness are premised on ZHP's June 20, 2018, notification of a potential unknown impurity being the alleged trigger for Teva's obligation to the issue an alert within three days. *See* **Ex. W**, TEVA-MDL2875-00565758 at -576; Barreto Dep. Vol. I at 251:22-254:1. But Teva placed a hold on sale of all ZHP API containing valsartan the very next day, June 21, 2018, and no such product was ever sold again that after date. *See* **Ex. X**, TEVA-MDL2875-00063796. Even assuming Plaintiffs are correct, and the Field Alert should have issued by June 23, 2018, it is irrelevant. No Plaintiffs in this trial paid for VCDs made with ZHP API after June 21—before the earliest claimed date the Field Alert could have been made. Therefore, any suggestion that the Field Alert was untimely is irrelevant and would serve no purpose other than to inflame the jury and unfairly prejudice Teva. *See* Fed. R. Evid. 403.

Additionally, introduction of this argument would force Teva to put forth its ample evidence that the July 3, 2018, Field Alert was timely. Specifically, on June 20, 2018, ZHP first notified Teva of the presence of a "previously unknown impurity that may have genotoxic potential" in ZHP's valsartan API. *See* **Ex. W**, TEVA-MDL2875-00565758 at -5763. No more specifics related to the identity of the impurity or scope of the impacted API was provided. On June 25, 2018, Teva first received notice that the "unknown impurity" may be NDMA when it received ZHP's full evaluation and root cause analysis. *See* **Ex. K**, TEVA-MDL2875-00041861. On June 28, Teva's quality department determined that a reportable event had occurred. *See, e.g.*, Barreto Dep. Vol. I. 130:13-131:14, 132:18-133:12, 138:15-139:13. Following federal regulations and its own SOPs, within three business days, on Tuesday, July 3, 2018, it notified the FDA in a Field Alert. *See, e.g.*, *id*. Notably, the FDA never challenged or complained about the timing of Teva's reporting. *See* Barreto Dep. Vol. II 727:9-728:17. Plaintiffs apparently disagree with the FDA (as evidenced by the unsupported assertion in their Statement of "Undisputed Facts"), but permitting them to make the unsupported argument that Teva should have initiated the Field Alert sooner would lead to an irrelevant detour into an issue that need not be resolved to address any claims actually at issue. Such argument would also risk confusing the jury into believing it is a dispute it must resolve.

K. Evidence Related to Teva Sales Outside the United States Post-Recall Should Be Excluded.

Teva anticipates that Plaintiffs may reference sales of Teva valsartan in markets outside the United States after the July 2018 recall of their VCDs manufactured with ZHP-API. For example, Plaintiffs questioned Dan Barreto at deposition about "[sales of] valsartan finished-dose products in other countries when that product might contain NDMA that's above the FDA interim limits[.]" *See* Barreto Dep. Vol. II 581:11-14; *see also* **Ex. Y**, TEVA-MDL2875-00024041. But critically, Mr. Barreto testified these considerations excluded the United States (and European markets) and depended on allowance by the distinct regulatory schemes in those other countries in an effort to manage supply issues impacting patient safety. *See, e.g., id.* at 581:9-584:2. As such, admission of such evidence would require Teva to defend its actions through evidence that the sales were appropriate within the framework of the foreign jurisdiction. This endeavor would not aid the jury in its determination of any fact at issue. Indeed, as discussed, the Court held in its Macro Discovery Order that Plaintiffs were not even entitled to *discovery on* "foreign regulatory documents sent or received regarding Valsartan or the Valsartan recall." *See* Macro Discovery Order, a 2. Evidence regarding foreign regulations is no more relevant in this trial, which involves products marketed only in the United States and regulated only by the FDA. Any decisions by Teva made in accordance with foreign regulatory authorities is irrelevant and should be excluded. *See In re*

Seroquel Prods. Liab. Litig., 2009 WL 223140, at *5-6 (M.D. Fla. Jan 30, 2009) (excluding evidence that could only show "a different regulatory authority, applying different standards in a different social and medical landscape, reached a conclusion different than the conclusion reached by the FDA under the U.S. system").

Further, any probative value would be outweighed by the potential to mislead the jury and waste time. *See Burns v. AstraZeneca Pharms. LP* 601 F. Supp. 2d 1313, 1318 (M.D. Fla. 2009) (barring evidence of foreign regulatory actions because "without providing context concerning the regulatory schemes and decision-making processes involved" it "would strip the jury of any framework within which to evaluate the meaning of that evidence . . . [and] result in a series of mini-trials regarding the grounds for the decisions and the regulatory schemes of the three foreign countries involved. This would confuse the jury and waste everyone's time."). Such jury confusion could also prejudice Teva if jurors are led to believe that Teva sold valsartan in other countries in violation of those countries' regulations, which it did not. Such an implication would serve no purpose other than to unfairly inflame the jury against Teva. *See* Fed. R. Evid. 403.

L. Reference to Destruction of Potential Destruction of Recalled Product or API Should Be Precluded.

The Court should preclude exclude reference, evidence, or testimony relating to destruction or potential destruction of recalled valsartan API and finished dose products. Such evidence is irrelevant and will waste time and mislead the jury.

Evidence related to the disposition of recalled product lacks any probative value to Plaintiffs' claims. Despite this, Teva anticipates Plaintiff will try to argue that Teva somehow wrongfully intended to destroy evidence or prevent testing of product by presenting emails discussing destruction of recalled valsartan product. **Ex. Z**, January 4, 2019 Email from Dellarese Herbert, TEVA-MDL2875-00481794; **Ex. AA**, August 16, 2019 Teva Monthly Recall Update to FDA, TEVA-MDL2875-00095841; Osmian Dep. at 194:20-199:12.

As a threshold matter, Teva does not dispute that its recalled product at issue in this trial manufactured with ZHP's valsartan API contained detectable levels of nitrosamines. And Plaintiffs do not assert that the specific levels found in any given lot, batch, bottle, or pill of VCDs are relevant to their claims, which are predicated on the theory that *any* detectable amount of NDMA rendered *all* VCDs similarly worthless. *See, e.g.*, **Ex. BB**, Deposition of Rena Conti (July 13, 2023) 239:20-240:1 ("I was asked to assume that there was material noncompliance and misbranding across products, across manufacturers. I was not asked to form an opinion on whether there were differences between products or between manufacturers.").

The Court previously considered and denied Plaintiffs' attempt to make an issue of the routine, non-prejudicial destruction of recalled product by Teva in the context of seeking further discovery on Teva's legal hold. *See* **Ex. DD,** 5.12.2021 Hrg Tr. at 50:7-64:13. The Court specifically found that Plaintiffs were not

prejudiced due to the lack of ability to test any and all at-issue product. *Id.* at 63:25-64:6. A similar rationale applies here, as Plaintiffs' claims are not predicted on knowledge of the impurity levels in any particular lot of VCDs. Moreover, to the extent Plaintiffs may now assert at the eleventh hour that such information is relevant, or that Teva has failed to adequately preserve evidence to allow them to pursue their claims, Teva confirmed to Plaintiffs on June 10, 2021, that Teva had retained samples of between 150 and 360 pills stored according to approved specifications for every single lot of at-issue valsartan product, and asked Plaintiffs to identify any products which Plaintiffs intended to test. *See* **Ex. CC**, S. Harkins 6.10.2021 email to D. Stanoch. In the more than two-and-a-half years since that correspondence Plaintiffs have not responded or sought testing of a single pill.

Therefore, as Plaintiffs had ample opportunity to test and chose not to, any reference to alleged destruction of product is not relevant, has no probative value, and would only seek to mislead the jury that there was any attempt to destroy evidence or prevent testing on Teva's part. *See Indemnity Ins. Co. of N. Am. v. Liebert Corp.*, 96 Civ. 6675(DC), 1998 WL 363834 (S.D.N.Y. June 29, 1998) (denying spoliation sanction where defendant had an opportunity to inspect evidence prior to its destruction).

To the extent Plaintiffs seek to introduce evidence related to Mylan API located at Teva's facility in Israel which was destroyed in the ordinary course

following the recalls, any alleged relevance is even further attenuated. *See* Barreto Dep. Vol. II at 651:8-654:24. This material: (1) was not ever incorporated into finished dose product sold by Teva or purchased by Plaintiffs; (2) is not the API at issue in this trial; (3) was not at any time located at a facility used to manufacture the relevant ZHP API product; and (4) was impacted by a different nitrosamine impurity (NDEA) not at issue in this trial.

Plaintiffs' only goal in introducing evidence that Teva, in the ordinary course of business, destroyed valsartan products is to unfairly prejudice the jury against Teva for destroying recalled products which do not form any part of the basis for Plaintiffs' claims. Such evidence should be precluded entirely.

Dated: February 16, 2024

Respectfully submitted,

By: */s/ Gregory E. Ostfeld*

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on February 16, 2024, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ Gregory P. Coates
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